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7.

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,706	08/01/2003	James D. Marks	407T-895120US	5306
22434	7590	12/22/2006	EXAMINER	
BEYER WEAVER & THOMAS, LLP			MINNIFIELD, NITA M	
P.O. BOX 70250			ART UNIT	PAPER NUMBER
OAKLAND, CA 94612-0250			1645	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		12/22/2006	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/632,706	MARKS ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	N. M. Minnifield	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 29 June 2006.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1,8,17-36,38-57,97,104 and 113-117 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1,8,17-36,38-57,97,104 and 113-117 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_\_

## **DETAILED ACTION**

### *Response to Amendment*

1. Applicants' amendments filed June 29, 2006 and October 16, 2006 (claims) are acknowledged and have been entered. Claims 2-7, 9-16, 37, 58-96, 98-103, 105-112 and 118 have been canceled. Claims 1, 17-22, 29-36 and 97 have been amended. Claims 1, 8, 17-36, 38-57, 97, 104 and 113-117 are now pending in the present application. All rejections have been withdrawn in view of Applicants' amendment to the claims and/or comments, with the exception of those discussed below.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Claims 1, 8, 24-36, 38-57 97 and 104 are rejected under 35 U.S.C. 102(b) as being anticipated by Amersdorfer et al (Infection and Immunity, Sept. 1997, 65(9):3743-3752).

Amersdorfer et al discloses an isolated single-chain Fv (scFv) anti-botulinum neurotoxin type A (BoNT/A) antibody capable of neutralizing botulinum neurotoxin type A. The antibody of Amersdorfer et al specifically binds to an epitope of botulinum neurotoxin type A (BoNT/A) binding domain (Hc) (Abstract and Materials and Methods). The prior art anticipates the claimed invention.

4. Claims 1, 8, 24, 27-36, 38-57 97 and 104 are rejected under 35 U.S.C. 102(b) as being anticipated by Chen et al (Infection and Immunity, May 1997, 65/5:1626-1630).

Chen et al disclose an isolated single chain antibody and that these antibodies bind to BoNT/A and neutralizing antibodies against botulism poisoning (abstract; p. 1627; p. 1626; p. 1630). The prior art anticipates the claimed invention.

5. Claims 1, 8, 17-22, 29-36, 38-46, 50-57, 97, 104 and 113-117 are rejected under 35 U.S.C. 102(b) as being anticipated by Amersdorfer et al (Vaccine 22 February 2002, 20:1640-1648) or Mullaney et al (Infection and Immunity, Oct. 2001, 69/10:6511-6514).

Amersdorfer et al, for example, discloses an isolated single chain antibody against botulinum neurotoxin type A (abstract; p. 1641, left column; materials and methods, p. 1641). These antibodies bind to and neutralize BoNT/A (p. 1641, left column; p. 1647, right column). The prior art anticipates the claimed invention.

6. Claims 1, 8, 17-22, 29-36, 38-43, 50-57, 97, 104 and 113-117 are rejected under 35 U.S.C. 102(b) as being anticipated by Bavari et al (Vaccine 22 February 2002, 20:1640-1648).

Bavari et al discloses isolated antibodies that neutralize BoNT/A and that mAb against BoNT/A were isolated and cloned (abstract; p. 1851, left column; materials and methods; p. 1852, left column). The prior art anticipates the claimed invention.

7. The prior art rejections set forth in paragraphs 3-6 above have been maintained for the reasons of record. Applicant's arguments filed June 29, 2006 have been fully considered but they are not persuasive. Applicants have asserted that the priority date of the present application is August 31 1998. As clearly stated in paragraph 0001 of the application:

[0001] This application claims priority to and benefit of USSN 60/400,721, filed on August 1, 2002, and is also a continuation-in-part of USSN 09/144,886, filed on August 31, 1998, both of which are incorporated herein by reference in their entirety for all purposes.

Applicants have also asserted that the following references cited by the Examiner were published after the priority date of the present application or less than one year before the priority date and are therefore unavailable as prior art under 35 U.S.C. §102(b): Amersdorfer et al. (1997) Infection and Immunity 65(9): 3743-3752; Amersdorfer et al. (2002) Vaccine, 20:1640-1648; Mullaney et al. (2001) Infection and Immunity, 69(10): 6511-6514; Baravi et al. (2002) Vaccine, 20: 1640-1648.

However, it is noted that the pending application is a continuation-in-part of 09/144866. Upon review of 09/144886 and 60/400721, it is noted that the instantly claimed invention is not set forth in these applications. The claimed clone huC25 and those sequences claimed (SEQ ID NO: 86-89, 126-128, 156-159, 196-198) are not disclosed in 09/144866 or 60/400721. Clone huC25 is not listed in Table 4 or 9, only in Table 11, which was first disclosed in the pending application along with Example 4. Therefore, the instantly claimed invention has an effective filing date of August 1, 2003, the date 10/632706 was filed.

With regard to Chen et al, Applicants have asserted that Chen et al does not disclose all of the claim limitations. Applicants have asserted that Chen et al does

not disclose an isolated human antibody that neutralizes BoNT/A as claimed. However, it is noted that Chen et al does disclose isolated single chain antibodies that bind epitopes in the variable heavy and variable light regions (see table 1 of Chen et al). The antibodies bind to epitopes specifically bound by antibodies expressed in a clone, the same or similar variant. Chen et al teaches the use of a human clone as claimed as well as methods of making (see methods and materials). With regard to “wherein said antibody binds to and neutralizes BoNT/A” and “wherein said antibody binds both A1 and A2 toxin”, it is noted that these wherein clauses add nothing to the patentability or substance of the claim. These recited properties are inherent. Further, since the Patent Office does not have the facilities for examining and comparing applicants' antibodies with the antibodies of the prior art reference, the burden is upon applicants to show a distinction between the material structural and functional characteristics of the claimed antibodies and the antibodies of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594. Applicants have not provided any side-by-side comparison(s) to show that the antibodies of the prior art of Chen et al differ from that of the claimed antibodies. Therefore, Chen et al anticipates the claimed invention.

8. No claims are allowed.

9. Applicants note that the Examiner's handling of the election of Group I in the response filed on August 31, 2005 (Examiner assumes this date should be September 6, 2005) is improper. However, it is not clear what was improperly handled. Linking claims 1, 37 and 97 have been examined. Applicants did not set

forth any arguments to the restriction requirement in the response filed August 31, 2006.

**10. THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

**11.** Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 571-272-0860. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



N. M. Minfield  
Primary Examiner  
Art Unit 1645

NMM  
December 17, 2006